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We aim to ensure that scientific discoveries translate into real-world innovations that benefit patients and society.

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Professor Guangjin Pan, Managing Director of the Centre for Regenerative Medicine and Health (CRMH), discusses how the center's focuses on translating cutting-edge science into clinical and commercial success – driving Hong Kong's ambition to become a global biotech hub. As Part of the Hong Kong Institute of Science & Innovation under the Chinese Academy of Sciences, CRMH pioneers breakthroughs like Neu-001, the first InnoHK small-molecule therapy to secure US FDA approval.

How was the Centre for Regenerative Medicine and Health established, and how does your background support its mission?

The Centre for Regenerative Medicine and Health (CRMH) is part of the Hong Kong Institute of Science & Innovation (HKISI), the Hong Kong branch of the Chinese Academy of Sciences (CAS). Established in 2019 with support from the Hong Kong government's InnoHK initiative – an effort to strengthen the city's scientific and innovation landscape – CRMH stands out as one of the few centres also financed by CAS. Our work focuses on regenerative medicine, addressing diseases beyond the reach of conventional therapies, while placing strong emphasis on translation: advancing scientific breakthroughs into commercial applications. A key aspect of our mission is to

generate intellectual property, foster spin-offs, and contribute to Hong Kong's growing biomedical sector.

Before taking up the role of Managing Director in 2020, I was a professor at the Guangzhou Institutes of Biomedicine and Health (GIBH), a leading CAS research institute. My research has centred on stem cell biology and regenerative medicine, particularly the differentiation of stem cells into specialised cells to replace damaged tissues, such as regenerating neural cells after stroke. More recently, my work has expanded to engineering natural killer (NK) cells, crucial components of the innate immune system that eliminate virus-infected or cancerous cells. Given the age-related decline in NK cell numbers, this research holds promise for cancer prevention and infectious disease management in ageing populations. In Hong Kong, I have continued these efforts with a strong focus on translational outcomes, in full alignment with CRMH's dual mission of scientific advancement and commercial impact.

What areas of therapeutic focus define CRMH's research agenda, and what early translational successes have been achieved?

At CRMH, oncology is a primary focus, with research efforts centred on developing immune cell therapies capable of addressing a broad range of cancers. By engineering NK cells as well as other immune cells such as macrophages andT cells to target malignant biological signatures, CRMH seeks to create versatile immunotherapeutic solutions to eliminate cancerous growths. These approaches aim to address the urgent needs for more generalisable and effective treatments across multiple tumour types.

In addition to oncology, CRMH is advancing therapies for neurological disorders based on neural regeneration. In collaboration with City University of Hong Kong, the centre developed Neu-001, a first-in-class small-molecule therapy targeting amblyopia, commonly known as 'lazy eye'. Amblyopia occurs when impaired visual input during early childhood disrupts the development of the brain's vision centres, often leading to irreversible vision loss. Neu-001 mimics visual stimuli, allowing the continued maturation of neural pathways until corrective interventions become possible. The therapy achieved a significant milestone by securing Investigational New Drug (IND) approval from the US FDA, representing the first chemical drug candidate under Hong Kong's InnoHK initiative to enter FDA-approved clinical trials. NeuDirection, a Hong Kong-based spin-off established by CRMH's Professor Micky Tortorella in partnership with Professor Jufang He from City University of Hong Kong, is now leading Neu-001's Phase I clinical development.

What milestones has CRMH reached over the past five years in advancing its scientific and clinical ambitions?

Over the past five years, CRMH has firmly established itself as a catalyst for translational innovation within Hong Kong's biomedical landscape. A major achievement has been the creation of a dedicated drug discovery platform, which not only supported the advancement of Neu-001 but also laid the groundwork for a broader pipeline of therapeutic candidates. Securing FDA IND approval for Neu-001 within a condensed timeframe exemplifies the centre's ability to translate foundational research into clinical opportunities with real-world impact.

In parallel, CRMH has advanced cell-based immunotherapy by developing a scalable platform for the directed differentiation of pluripotent stem cells (PSCs) into highly specific, functional immune cells. Building on the pioneering work of Dr. James Thomson, who first isolated human embryonic stem cells in 1998 and set up the culture condition for human PSCs, the centre has focused on generating pure, homogeneous populations essential for clinical application from human pluripotent stem cells (hPSCs). These efforts have culminated in the production of NK cells as well as other immune cells such as macrophages capable of recognising and destroying malignant cells with precision. CRMH is now preparing to scale this platform under FDA-compliant manufacturing standards, paving the way for the clinical development of next-generation cell-based therapies aimed at redefining cancer treatment.

How is CRMH structuring its regulatory strategy to support international clinical development?

CRMH is pursuing a global regulatory strategy, engaging with US FDA, the European Medicines Agency (EMA), and China's National Medical Products Administration (NMPA). Aligning with these international standards enables clinical trials conducted in Hong Kong to achieve international recognition, broadening the global reach of our innovations. Additionally, Hong Kong offers strategic logistical advantages, allowing therapies produced locally to be exported internationally with fewer restrictions than those manufactured in mainland China.

Our objective is to secure US FDA approval to initiate clinical trials while simultaneously working towards NMPA authorisation for eventual clinical application in China, ensuring that CRMH's therapies are positioned to serve both regional and global healthcare needs.

How does CRMH approach the commercialisation of its research, and what is its current capacity for advancing development programmes?

CRMH was founded as a research institute rather than a commercial entity, with a core mission to generate scientific innovation and translate discoveries into industrial applications through the licensing of IP. Our commercialisation strategy is intentionally flexible: researchers can establish companies in Hong Kong, licensing IP from the centre and independently raising development capital, or CRMH may collaborate directly with established pharmaceutical and biopharmaceutical companies in joint initiatives. Both pathways are fully supported by the Hong Kong government, provided the IP translation strengthens the local innovation ecosystem. In most cases, CRMH prefers straightforward licensing agreements structured around milestone payments, maintaining the centre's research independence, although shareholding arrangements remain an option where appropriate. Once IP is transferred, development activities are typically carried out by the licensee companies, while CRMH retains the possibility of continued collaboration in complementary research areas.

At present, CRMH oversees more than ten active research programmes across oncology, central nervous system (CNS) disorders, and other therapeutic areas, each offering strong potential for further development and commercialisation. A dedicated committee under the Hong Kong government's InnoHK initiative oversees project selection, ensuring that only those proposals demonstrating robust scientific merit and clear translational potential progress towards development. This structured, merit-driven approach allows CRMH to maintain a dynamic pipeline aligned with both academic excellence and global healthcare needs.

What are CRMH's strategic goals for the next five years, and how is the centre building capacity to achieve them?

Over the next five years, the Centre is focused on deepening its translational impact by establishing more than ten successful spin-off companies founded on its scientific discoveries. Success will be measured not simply by the transfer of IP but by the ability of these companies to achieve commercial viability and contribute meaningfully to the healthcare sector. This shift reflects a pragmatic approach, moving beyond academic metrics such as publication volume to tangible outcomes that demonstrate real-world impact.

To support this objective, CRMH has established a dedicated business development team composed of professionals with private sector expertise, tasked with identifying strategic partners, facilitating IP licensing, and ensuring that research innovations are actively translated into market-ready solutions. By strengthening its commercialisation infrastructure, CRMH aims to drive innovation beyond the laboratory, contributing to the growth of Hong Kong’s emerging biotech ecosystem and delivering tangible benefits to patients and society.

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